K123268

NOV 7 2012

1 General Information

Submitter Name/Address

ArthroCare Corporation
7000 West William Cannon Drive
Austin, TX 78735

Contact Person: Cheryl Frederick
Director, Regulatory Affairs

Contact Number(s) and Email Address:
Direct: 512-391-5751
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Manufacturing Facilities

ArthroCare Corporation
15285 Alton Parkway, #200
Irvine, CA 92618

ArthroCare Costa Rica
502 Parkway, Global Park
La Aurora, Heredia
Costa Rica

Establishment Registration Numbers

Austin, TX: 3006524618
Irvine, CA: 2032380
Costa Rica: 3003780898

Sterilization Facility

SteriGenics Corporation
7775 S. Quincy
Willowbrook, IL 60527

Device Identification (System Components)

The SmartStitch PerfectPasser System is a Class II device consisting of the following components:

Trade/Proprietary Name: SmartStitch® PerfectPasser® Connector
Classification Name: Suture Passer
Product Code: NBH
CFR Section: 21 CFR 888.1100
Device Class: Class I
Classification Panel: Orthopedic

Trade/Proprietary Name: SmartStitch® Handle
Classification Name: Suture Passer (Handle)
Product Code: NBH
CFR Section: 21 CFR 888.1100
Device Class: Class I
Classification Panel: Orthopedic

Trade/Proprietary Name:	Suture Cartridge containing Suture
Classification Name:	Suture, Nonabsorbable, Synthetic, Polyethylene
Product Code:	GAT
CFR Section:	21 CFR 878.5000
Device Class:	Class II
Classification Panel:	General & Plastic Surgery

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Arthrocare Corporation
% Ms. Cheryl Frederick
Director, Regulatory Affairs
7000 West William Cannon Drive
Austin, Texas 78735

November 7, 2012

Re: K123268
Trade/Device Name: SmartStitch® Perfect Passer® System
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable polyethylene terephthalate surgical suture
Regulatory Class: Class II
Product Code: GAT, NBH
Dated: October 18, 2012
Received: October 19, 2012

Dear Ms. Frederick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123268

Device Name: SmartStitch® PerfectPasser® System

Indications for Use:

The SmartStitch® PerfectPasser® System is indicated for use in the placement of suture(s) through soft tissue in arthroscopic and limited access procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K123268